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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/135,183	08/17/1998	CYNTHIA C. BAMDAD	A-65909-1/RF	8993

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BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
1631	

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24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/136,183	Applicant(s) Bamdad
	Examiner Michael Borin	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Dec 14, 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) Other: _____

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DETAILED ACTION

The Examiner of record of this application has changed. Please address correspondence to Examiner M. Borin, AU 1631.

Rejections not reiterated from previous Office actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

The Examiner acknowledges amendment filed 12/14/01. Claims 23-25 are added. Claims 3-10, 12-20 are amended. Claims 1-25 are pending.

Information Disclosure Statement

Applicants' Information Disclosure Statement filed 6/25/01 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed are directed to a composition comprising a target sequence or to a method utilizing thereof. A sequence is not a statutory subject matter. As opposed to, for example, polynucleotide having certain sequence, a sequence by itself is a written representation of a real product. Therefore, the claimed composition is not a composition of matter and, thus, the invention is directed to non-statutory subject matter.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-25 (and claims dependent thereupon) are rejected under 35 U.S.C. 112, first paragraph, because the best mode contemplated by the inventor has not been disclosed. The invention as disclosed in specification, requires a self-assembled monolayer of the electrode to be comprised of conductive oligomer; the latter is now omitted from claims 23-25.

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Claims 23-25 (and claims dependent thereupon) are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for electrodes which comprise monolayer comprising conductive oligomer, does not reasonably provide enablement for electrodes comprising non-conducting oligomer (e.g., oligomer comprising -CH₂- groups).. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321[©] may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 20-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-35 of U.S.

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Patent No. 6096273. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 6096273 are drawn to a composition comprising an

- an electrode;
- a conductive oligomer which forms monolayer (see also col. 8 +);
- a first nucleic acid (which reads on "capture probe" of the instant invention as any nucleic acid is capable of hybridizing to other nucleic acids and, as such, to serve as "capture probe");
- a second nucleic acid comprising ETM moiety (which reads on "label probe" or "target sequence" of the instant invention).

The reference differs from the instant invention as claimed in that it does not specify that the monolayer is self-assembled. However, the "self-assembly" is related to method of making, rather than to composition itself. As such, the instant claims are in product-by-process format, and as such, it is the novelty and patentability of the instantly claimed product that need to be established and not that of the recited process steps. Furthermore, although the reference does not teach the "self-assembly" of the monolayer, the oligomer described in the reference are from the same genus as those of the instant invention and, hence, are as capable of "self-assembly".

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Claim Rejections - 35 USC § 103

Applicant has provided evidence in this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as US Patent 6,096,273 at the time this invention was made. Accordingly, 6,096,273 is disqualified as prior art through 35 U.S.C. 102(f) or (g) in any rejection under 35 U.S.C. 103(a) in this application. However, this applied art additionally qualifies as prior art under subsection (e) of 35 U.S.C. 102 and accordingly is not disqualified as prior art under 35 U.S.C. 103(a).

Applicant may overcome the applied art either by a showing under 37 CFR 1.132 that the invention disclosed therein was derived from the invention of this application, and is therefore, not the invention "by another," or by antedating the applied art under 37 CFR 1.131.

Claims 1-10, 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6096273. Patent No. 6096273 teaches composition comprising:

- an electrode;
- a conductive oligomer which forms monolayer (see also col. 8 +);
- a first nucleic acid (which reads on "capture probe" of the instant invention as any nucleic acid is capable of hybridizing to other nucleic acids and, as such, to serve as "capture probe");

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- a second nucleic acid comprising ETM moiety (which reads on "label probe" or "target sequence" of the instant invention).

The reference differs from the instant invention as claimed in that it does not specify that the monolayer is self-assembled. However, the "self-assembly" is related to method of making, rather than to composition itself. As such, the instant claims are in product-by-process format, and as such, it is the novelty and patentability of the instantly claimed product that need to be established and not that of the recited process steps. Furthermore, although the reference does not teach the "self-assembly" of the monolayer, the oligomer described in the reference are from the same genus as those of the instant invention and, hence, are as capable of "self-assembly".

Claim Rejections - 35 USC § 102.

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-10,23,24 are rejected under 35 U.S.C. 102(b) as anticipated by Dong et al. (Bioelectrochem. Bioenerg., 42(1), 7-13, 1997) or Duan et al. (Anal. Chem., 66(9), 1369-77, 1994)

The instant claims are drawn to a composition comprising an electrode comprising a self-assembled monolayer of conductive oligomer and a capture probe, and another compound (identified as either a target sequence or a label probe).

Dong et al. teach biological compounds, such as cytochrome c, cytochrome c oxidase and horseradish peroxidase (HRP), immobilized covalently to the self-assembled monolayers of 3-mercaptopropionic acid on a gold electrodes. The biological compounds communicate directly electrons with the electrode surface without mediators and keep their physiological activities. Such biosensors can be used for detection of analytes, such as H₂O₂, glucose and cholesterol.

Duan et al. teach enzyme immunoassay for proteins based on using electrochemical detection system that enables preferential measurement of surface-bound enzyme-labeled antibody. The capture monoclonal antibody is immobilized on gold electrode via a self-assembled monolayer of thioctic acid. Both model analyte protein (human chorionic gonadotropin; hCG) and alkaline phosphatase-labeled anti-hCG (ALP-Ab) are incubated simultaneously with the immobilized capture anti-hCG antibody. Surface-bound ALP-Ab is spatially

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resolved from the excess conjugate in the bulk sample solution by introducing the enzyme substrate through the back side of the porous electrode membrane.

Dong et al, and Duan et al references represent vast amount of prior art teaching electrochemical assays utilizing capture protein (or antibody) immobilized on electrode covered with self-assembled layer comprising conductive oligomer. Such protein biosensors are then capable of interacting with another ligand (e.g., protein or substrate).

In regard to the instant claim's language "capable of hybridizing", hybridizing is understood as ability to form a macromolecular hybrid; such ability is applicable to either polynucleotides or polypeptides. See Oxford Dictionary of Biochemistry and Molecular Biology, 1997, p. 311.

In regard to the presence of electron transfer moiety on the "target sequence" or 'label probe", each reference teaches electron transfer between ligand and electron; further, majority of protein contain residues such as tryptophane which are capable for electron transfer.

Prior art made of record

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Saito et al., Mirsky et al., Higgins et al., Schlereth et al., Wallace et al., Ha et al., Li et al.

Conclusion.

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February 21, 2002

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

mlb

